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REMARKS

Claims 1-11 are pending, and claim 12 has been cancelled.

Claim 1 has been amended to add a limitation requiring that the affinity molecule-analyte complexes form in a liquid phase. The importance of this limitation, as discussed below, is believed to distinguish from Nedved's method, where the complexes are formed in an insoluble phase, e.g., protein-G agarose column. The amendment is amply supported by the specification; e.g., bottom page 4 to top page 5; and examples.

In addition, further amendments to claim 11 merely put the claim in a form where the steps are perhaps easier to delineate.

Anticipation by Nedved

Claims 1-11 are rejected for allegedly being anticipated by Nedved.

Applicants would remind the Examiner that anticipation requires that each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference, and, further, that the absence in the prior art reference of even a single claim element precludes a finding of anticipation. In re Robertson, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999); MPEP § 2131 (Emphasis added).

Nedved's method involves immobilizing antibodies on an insoluble Protein G coupled support, whereas amended claim 11 requires that the affinity molecule-analyte complexes form in a liquid phase. This difference in forming affinity molecule-analyte complexes is sufficient to find the claimed subject matter patentable over the Nedved reference, because Nedved does not explicitly or inherently teach the formation of affinity molecule-analyte complexes in solution.

Applicants' method allows for the determination of virtually any analyte that is capable of binding an affinity molecule, e.g., enzyme, receptors, etc, because the binding occurs in solution, and unhindered by interactions with the support column. However Nedved only teaches forming affinity molecule-analyte complexes comprising an antibody having Fc domains required to bind to insoluble Protein G supports.

Thus, Nedved's method is restricted to isolating analytes for which each affinity molecule is an antibody that binds to Protein G columns. However, even if non-antibody affinity molecules were used, it would still be required to have a functional immobilization scheme for coupling the affinity molecule to the insoluble support material.

Applicants' method avoids this problem.

The aforementioned problem is even more serious when the affinity molecule of interest is an integral membrane protein having receptor-like and/or enzyme-like properties. It is well known in the biochemical arts that maintaining the solubility and functionality of integral membrane proteins is complicated, because of their hydrophobic nature. When these proteins are removed from lipid bilayers during purification, their tendency is to assume a different and often nonfunctional, configuration.

However, the unstable conformation of purified membrane proteins presents far more serious problems when used in Nedved's method. One problem is that the conditions for chemical modification of these proteins to enable attachment to a support, must leave the proteins in a functional and soluble state. Further, the protein must not interact with the support in a manner that adversely effects its analyte-binding function. For example, it is known that hydrophobic regions of proteins will tend to interact with various support materials.

In sum, because Nedved depends on affinity molecule immobilization, the aforementioned problems would very likely narrow the scope of the method's use and would time delays in assay development. In contrast, persons of ordinary skill that compare the methods would likely conclude that Applicants' method would be expected to provide less technical problems while being more versatile than Nedved's.

For these reasons, it is respectfully requested that rejection be withdrawn.

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CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Applicants request that this be considered a petition therefore. Please charge the required fee to Deposit Account No. 14-1263.

ADDITIONAL FEES

Please charge any further insufficiency of fees, or credit any excess to Deposit Account No. 14-1263.

Respectfully Submitted,

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